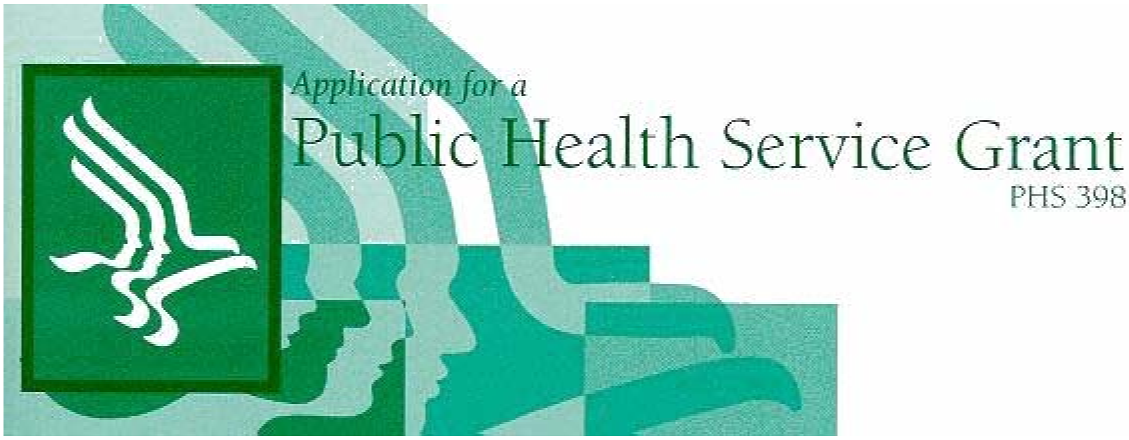

SBIR/STTR Supplementary Instructions
for
Completing the Newly Revised (09/2004)
PHS 398 Forms

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IMPORTANT CHANGES FOR PREPARING SBIR/STTR GRANT APPLICATIONS USING THE REVISED 9/2004 PHS 398 FORMS

CHANGES

Following is a summary of policy changes and notifications that have been implemented since the release of the last PHS 398 (05/01 version). These changes have been incorporated into the 9/2004 version of the PHS 398 application.

Title	NIH Guide Link
NIH ANNOUNCES REVISED POLICY: APPLICATIONS THAT INCLUDE CONSORTIUM/CONTRACTUAL FACILITIES AND ADMINISTRATIVE COSTS *Revised policy now applies to all applications involving consortium/contractual F&A costs, solicited & investigator-initiated, regardless budget amount or budget format.*	NOTICE: NOT-OD-05-004 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html
NIH ANNOUNCES UPDATED CRITERIA FOR EVALUATING RESEARCH GRANT APPLICATIONS *NIH Peer Review Criteria modified to better accommodate interdisciplinary, translational, and clinical projects.*	NOTICE: NOT-OD-05-002 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html
NIH POLICY ON SHARING OF MODEL ORGANISMS FOR BIOMEDICAL RESEARCH *New Policy on Sharing Model Organisms*	NOTICE: NOT-OD-04-042 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html
PUBLICATION OF THE REVISED NIH GRANTS POLICY STATEMENT (REV. 12/03)	NOTICE: NOT-OD-04-009 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-009.html
NIH SUPPORT FOR SCIENTIFIC MEETINGS AND CONFERENCES *NIH has established specific submission dates for conference grant applications (April 15, August 15, December 15) and requires advance approval from an IC for submission.*	PAR-03-176 http://grants.nih.gov/grants/guide/pa-files/PAR-03-176.html
REQUIREMENT OF DUNS NUMBER *A Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is required on applications for Federal grants or cooperative agreements.*	NOTICE: NOT-OD-03-055 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-055.html

Title	NIH Guide Link
REVISED NIH POLICY ON SUBMISSION OF A REVISED (AMENDED) APPLICATION *Eliminates the two-year time frame to submit up to two amended applications.*	NOTICE: NOT-OD-03-041 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html
REMINDER AND CLARIFICATION – DELIVERY OF COMPETING GRANT, COOPERATIVE AGREEMENT, AND FELLOWSHIP APPLICATIONS *Clarifies zip code for U.S. Postal Service express mail vs. courier service express mail.*	NOTICE: NOT-OD-03-040 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html NOTICE: NOT-OD-02-012 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html
NOTICE OF LEGISLATIVE MANDATES CONTAINED IN THE FY 2003 CONSOLIDATED APPROPRIATIONS RESOLUTION P.L. 108-07; SIGNED FEBRUARY 20, 2003 *Acknowledgment of Federal Funding; Anti-Lobbying; Continued Salary Limitation; Ban on Funding of Human Embryo Research; Purchase of American-Made Equipment and Products; Limitation on Use of Funds for Promotion of Legalization of Controlled Substances* *Restriction on Distribution of Sterile Needles; Restriction on Abortions*	NOTICE: NOT-OD-03-035 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-035.html *NIH updates this notice annually in the NIH Guide for Grants and Contracts.*
FINAL NIH STATEMENT ON SHARING RESEARCH DATA *Applications with direct costs greater than $500,000 in any single year, or if specifically required by the RFA, must address data-sharing in the application.*	NOTICE: NOT-OD-03-032 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html
RESUBMISSION OF UNPAID RFA APPLICATIONS AND RESUBMISSION OF APPLICATIONS WITH A CHANGED GRANT ACTIVITY MECHANISM *Changes policy on new vs. amended applications.*	NOTICE: NOT-OD-03-019 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html
LABORATORY ANIMAL WELFARE: CHANGE IN PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS *Implements Just-in-Time policy for Institutional Animal Care and Use Committee (IACUC) Approval Date.*	NOTICE: NOT-OD-02-064 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html

Title	NIH Guide Link
GRADUATE STUDENT COMPENSATION *NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level.*	NOTICE: NOT-OD-02-017 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html
REVISED POLICY ON THE ACCEPTANCE FOR REVIEW OF UNSOLICITED APPLICATIONS THAT REQUEST $500,000 OR MORE IN DIRECT COSTS *Implements six week advance window for NIH acceptance.*	NOTICE: NOT-OD-02-004 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html
AMENDMENT: NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH	NOTICE: NOT-OD-02-001 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html
REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS *Implements new requirement for education on the protection of human research participants for all individuals identified as Key Personnel.*	NOTICE: NOT-OD-01-061 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html
NIH POLICY ON REPORTING RACE AND ETHNICITY DATA: SUBJECTS IN CLINICAL RESEARCH	NOTICE: NOT-OD-01-053 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

CHANGES TO PHS 398 INSTRUCTIONS

In an effort to simplify the instructions, the PHS 398 (http://grants.nih.gov/grants/funding/phs398/phs398.html) has been restructured into three distinct parts. Instructional information related to the preparation, submission and review of your application is included in Part I: Instructions. Information relating to human subjects research is now in a separate section of the PHS 398, Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Information relating to policies and assurances, definitions and other *non-instructional* information is now is a separate section, Part III: Policies, Assurances, Definitions, and Other Information.

Font Size Requirement: NIH now requires the use of Arial-11 or Helvetica-11 point font.

NIH Peer Review Criteria: The Review Criteria have been updated to better accommodate interdisciplinary, translational, and clinical projects.

CHANGES TO PHS 398 APPLICATION FORMS

Form Page 1: Face Page

Item 1. The length of the title has been increased to 81 characters.

Item 3h. eRA Commons User Name field has been added.

If the principal investigator is registered in the eRA Commons, enter the assigned Commons User Name. This data item is currently optional

Item 4. Human Subjects Research box has been modified as follows:

- 4a: No/Yes check boxes for "Research Exempt"
- 4b: Human Subjects Assurance Number
- 4c: No/Yes checkboxes for Clinical Trial Check "Yes" or "No" to indicate whether the project is a clinical trial.
- 4d: No/Yes checkboxes for NIH-Defined Phase III Clinical Trial Check "Yes" or "No" to indicate whether the project is an NIH-Defined Phase III clinical trial.

Item 7. Costs Requested for Initial Budget Period

- **Item 7a.** Direct Costs Requested for Initial Budget Period

  Do *not* include amount requested for fee/profit.

  Non-Modular. From Form Page 4, enter the "Subtotal Direct Costs for Initial Budget Period".

  Modular, With Consortium/Contractual Costs. From the Modular Budget Format Page enter the "DC less Consortium F&A" for the initial period only.

  Modular, Without Consortium/Contractual Costs. From the Modular Budget Format Page enter "Total Direct Costs" for the initial period only.

- **Item 7b.** Total Costs Requested for Initial Budget Period

  Non-Modular. Enter the sum of: 1) the "Total Direct Costs for Initial Budget Period" from Form Page 4; 2) the requested Fee from Form Page 4; and 3) the Facilities and Administrative costs for the initial budget period, as calculated on the Checklist Form Page.

  Modular, With or Without Consortium/ Contractual Costs. Enter the sum of: 1) the "Total Direct Costs" for the initial period from the Modular Budget Format Page; 2) the requested Fee on the Modular Budget Format Page; and 3) the Facilities and Administrative costs for the initial budget period, as calculated on the Checklist Form Page.

  Note Item 7b represents total direct costs, including any consortium F&A costs.

Item 8. Costs Requested for Proposed Period of Support

- **Item 8a.** Direct Costs Requested for Proposed Period of Support

Non-Modular. From Form Page 5, enter the sum of "Subtotal Direct Costs" for all years.

Modular, With Consortium/Contractual Costs. From the Modular Budget Format Page, enter the "Sum Total" of "DC less Consortium F&A" for all years.

Modular, Without Consortium/Contractual Costs. From the Modular Budget Format Page, enter the "Sum Total" of "Total Direct Costs" for all years.

- **Item 8b.** Total Costs Requested for Proposed Period of Support

Non-Modular. Enter the sum of: 1) "Total Direct Costs" from Form Page 5; 2) the requested "Total Fee for Entire Proposed Project Period" on Form Page 5; and 3) the Facilities and Administrative costs for the proposed period of support, as calculated on the Checklist Form Page.

Modular, With or Without Consortium/ Contractual Costs. Enter the sum of: 1) "Sum Total" from the Modular Budget Format Page; 2) the requested Fee for the entire proposed period (on the Modular Budget Format Page); and 3) the Facilities and Administrative costs for the proposed period of support, as calculated on the Checklist Form Page.

Note Item 8b represents total direct costs, including any consortium F&A costs.

<u>Form Page 2:</u>

Form Page 2 is now two pages (Form Page 2 and Form Page 2-continued) which consist of five sections: Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells.

Do NOT insert additional pages between Form Page 1 and Form Page 2.

As part of the **Description**, instructions have been added to succinctly (2-3 sentences) describe the relevance of the proposed research to public health. This component of the Description should be prepared using concise terms and plain language that can be understood by a general, lay audience.

Description: Project Summary and Relevance

The first and major component of the Description is a **Project Summary**. It is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.

The second component of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to **public** health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

DO NOT EXCEED THE SPACE PROVIDED.

Do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the project description will be entered into an NIH database (Computer Retrieval of Information on Scientific Projects - CRISP) and will become public information.

Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there is more than one performance site, list all the sites, including Department of Veterans Affairs (V.A.) facilities and foreign sites, and provide an explanation on the Resources Format Page of the application. One of the sites indicated must be the applicant organization or be identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the Checklist Form Page of the application. State whether a consortium/ contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan.

If a performance site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the performance site operates under an appropriate OHRP-approved assurance for the protection of human subjects and complies with 45 CFR Part 46 and other NIH human subject related policies described in the PHS 398 and GPS.

For research involving vertebrate animals, the applicant organization must ensure that all performance sites hold OLAW-approved assurances.

Key Personnel

A field has been added for the eRA Commons User Name. This data item is currently optional.

In addition to the principal investigator (PI), Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Key Personnel. **Consultants should also be included if they meet the same definition.**

Key Personnel must devote measurable effort to the project whether or not salaries are requested. "Zero percent" effort or “as needed” are not acceptable levels of involvement for those designated as Key Personnel.

Start with the principal investigator. List the principal investigator’s **last name first**. All other Key Personnel should be listed in **alphabetical order**, last name first. For each individual provide name, eRA Commons User Name (if known), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

Other Significant Contributors

A category has been added to Form Page 2 that identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project.

This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion.

However, if an award is to be made, Other Support information will not be required or accepted since considerations of overlap do not apply to these individuals.

Should the level of involvement change for an individual listed in this category, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

Human Embryonic Stem Cells

Instructions have been added regarding projects that involve human embryonic stem cells. If the proposed project involves human embryonic stem cells, list in this section the registration number of the specific cell line(s) from the stem cell registry found at: http://stemcells.nih.gov/registry/index.asp. Use continuation pages as needed. If a specific line cannot be referenced at the time of application submission, include a statement that one from the registry will be used.

Changes and Instructions Pertaining to Budget Preparation

Modular Budget Format Page:

The budget fields have been modified to fully implement the new policy on Direct Cost Limitations. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html. Specifically, users must now separate the Consortium F&A costs from the other Direct Costs. Instructions have been revised to implement the new policy.

Modular, With Consortium/Contractual Costs. On the Modular Budget Format Page, enter separately the Direct Costs less Consortium F&A, Consortium F&A, and Total Direct Costs requested for each year. The budget figures from the "DC less Consortium F&A" row are used for Face Page Items 7a. and 8a.

Modular, Without Consortium/Contractual Costs. If your budget does not include consortium/contractual costs complete only the "Total Direct Costs" row. From this row, use "Initial Period" figure for Face Page Item 7a, and "Sum Total" figure for Face Page Item 8a.

Form Pages 4 and 5:

Budget pages have been modified to implement the new policy on Direct Cost Limitations. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html. Specifically, the "Consortium/Contractual Direct Costs" budget row has been moved to above the "Subtotal Direct Costs" line. Instructions have been revised to implement the new policy.

Specific instructions for preparing the SBIR or STTR budget are provided at the end of this document.

Biographical Sketch Format Page:

A field has been added for the eRA Commons User Name. This data item is currently optional.

Follow the format of the "Biographical Sketch Format Page." This section must contain the biographical sketches of *all KEY* personnel and Other Significant Contributors, *including consultants,* following the order as listed on Form Page 2.

If the individual is registered in the NIH eRA Commons, include the assigned Commons User Name. This data item is currently optional.

Use the sample biographical sketch format page, available at http://grants.nih.gov/grants/funding/phs398/phs398.html, to prepare this section for all (modular and other) grant applications.

Personal Data Form Page:

Applicants are now requested to provide **only** the last four digits of the Social Security Number. While providing this information remains voluntary, it is hoped that by limiting the data to only the last four digits, individuals will be more receptive to providing it. This data continues to provide the agency with vital information necessary for accurate identification, referral, and review of applications and for management of PHS grant programs.

Key Personnel Report Format Page:

The request for a Social Security Number is now limited to the last four digits.

Checklist Form Page:

A field has been added for "Change of Grantee Institution."

The form page also includes two distinct options for grants at Foreign Institutions or Domestic Grants with Significant Foreign Involvement. Also, a text entry field has been added to list the countries involved.

BUDGET INSTRUCTIONS FOR SBIR/STTR GRANT APPLICATIONS USING THE PHS 398 (REVISED 09/2004)

FOLLOW THESE INSTRUCTIONS FOR MODULAR FORMAT

Modular Budget Format Page (MS Word | PDF)

The following instructions are pertinent to all SBIR/STTR applications requesting *up to $100,000 total* (direct costs, F&A, and profit/fee). Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application. Under certain circumstances, additional budget information will be requested by the awarding component.

Note: The budget fields on the modular budget format have been modified. Specifically, users must now separate the Consortium F&A costs from the other Direct Costs. See sample SBIR/STTR modular format budget pages (SBIR STTR).

- Use for budget requests of $100,000 total (direct costs, F&A, and profit/fee) or less.
- Submit the Modular Budget Format Page and follow the specific modular instructions for SBIR or STTR, as applicable, which is to be *completed by the small business concern*.
- *Do not submit Form Pages 4 and 5. Use these as internal "worksheets" only* in the development of the total direct costs to be shown on the Modular Budget Format Page and in Item 7a of the Face Page.
- Do not make budget requests in increments of $25,000 (as is done for non-SBIR/STTR mechanisms.
- Request the amount of fee/profit in the narrative section of the Modular Budget Format Page. Since this is not a direct cost, do not factor the amount into the direct costs shown on the modular table.

The small business concern's F&A/Indirect Costs are to be shown on the Checklist Page. The TOTAL amount (sum of direct, F&A and fee) is to be shown on the Face Page in Items 7b and 8b.

- Refer to the Modular Budget Sample for SBIR (http://grants1.nih.gov/grants/funding/phs398/modbudgetsample_sbir.pdf) or STTR (http://grants1.nih.gov/grants/funding/phs398/modbudgetsample_sttr.pdf).

Modular Format Budget: Table

Present budget information in the table of the Modular Budget Format Page according to the following format:

Modular, With Consortium/Contractual Costs. On the Modular Budget Format Page, enter separately the Direct Costs less Consortium F&A, Consortium F&A, and Total Direct Costs requested for each year. The budget figures from the "DC less Consortium F&A" row are used for Face Page Items 7a. and 8a.

Modular, Without Consortium/Contractual Costs. If your budget does not include consortium/contractual costs complete only the "Total Direct Costs" row. From this row, use "Initial Period" figure for Face Page Item 7a, and "Sum Total" figure for Face Page Item 8a.

Modular Format Budget: Justification

Provide, *in narrative format*, the following information on Personnel, Consortium (Contractual and Consultant Costs) and Fee. *Use continuation page(s), if necessary*.

Personnel.

List **all** personnel, including names, percent of effort and roles on the project. Do not provide individual salary information. Since the request should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation. For guidance on current salary limitations, see the *[NIH Guide for Grants and Contracts](#)* on the NIH grants website (search on "salary limitation <year>", e.g., 2004).

Include the following information for personnel:

> ***Name of Each Individual.*** Starting with the principal investigator, list the names of *all* applicant small business personnel who are to be involved on the project, regardless of whether a salary is requested.
>
> ***Percentage Effort on Project.*** List the percentage of each individual's employment at the organization to be spent on *this project*. If an individual engages in other corporate responsibilities, such as management, the total percentage devoted to all research activities by the individual must be less than 100%. While a minimum percent effort is not stipulated for the principal investigator on an SBIR project, note that the principal investigator is the individual who is responsible for the scientific or technical aspects of the grant and for day-to-day management of the project.
>
> ***Role on Project.*** Identify the role (for example, principal investigator or statistician) of each individual listed on the project. The concept of co-principal investigator is not recognized.
>
> ***Description of each individual's specific functions.*** State the specific functions that each individual will devote to the project.

Consortium/contractual costs. Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest $1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the **total** consortium/contractual costs must be included in the overall requested modular direct cost amount.

> While all NIH ICs use modular formats, not all of the other PHS agencies accept modular budgets. If you are submitting an application to an agency other than NIH, be sure to read the instructions in the funding announcement to determine whether the application should be submitted in the modular format, or contact an official at the appropriate PHS awarding component.

Consultant Costs. Provide the names and organizational affiliations of any consultants, *other than those involved in contractual arrangements*, who have agreed to serve in that capacity. Include consultant physicians in connection with patient care. Briefly describe the services to be performed, including the number of days of anticipated consultation, and the total costs requested for each individual. *Letters of commitment from consultants and collaborators must be submitted with the application, but are excluded from the 25-page limitation*.

Fee

Explain the basis for the profit/fee requested. A reasonable profit/fee is available to small business concerns receiving awards under the SBIR/STTR program; however, this profit/fee must be included in your budget request at the time of application. *The amount of the fee approved by the agencies participating in this solicitation normally will not exceed 7% of total costs (direct and indirect) for each Phase (I and II) of the project*. The fee is not a "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. The profit/fee *applies solely to the small business concern* receiving the SBIR award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Modular Budget for STTR Applications

- Submit the *Modular Budget Format Page*, which is to be *completed by the Small Business Concern*. Follow the instructions above as described under "Modular Budget for SBIR Applications."

- Under the "Consortium" section of the *Modular Budget Format Page*, describe the work to be performed by the research institution and indicate the total costs (direct plus F&A). Also describe and indicate total costs pertaining to arrangements for work that will be performed by an organization other than the "research institution."

- *Also* submit the *STTR Research Institution Certification Format Page* (MS Word | PDF) to be completed by the single partnering *U.S. research institution*. Include signatures as requested and indicate the TOTAL COSTS (sum of direct and F&A costs) of the portion of the project to be performed by the research institution.

Do not submit the detailed Research Institution Budget Page, Form Page 4 or Form Page 5. Use these as internal "worksheets" only in the development of the total costs for the research institution.

Reminders. The principal investigator on an STTR project must devote a minimum of 10% effort to the project. The small business concern—the applicant organization—must perform at least 40% of the work on the STTR project and a single partnering research institution must perform at least 30% of the work. Deviations from the minimum percentage requirements for the small business concern and the single partnering research institution are **not** permitted.

A duly authorized representative at the single collaborating research institution must certify, at the time of application, that at least 30% of the work of the project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." For Modular Budgets, use the STTR Research Institution Certification Format Page.

FOLLOW THESE INSTRUCTIONS FOR NON-MODULAR FORMAT

The following instructions are pertinent to all applications requesting **more than $100,000 total (direct costs, F&A costs, and profit/fee).**

Submit detailed categorical budget information for the "Initial Budget Period" [Form Page 4 (MS Word | PDF)] and the "Entire Proposed Period of Support" Budget for Entire Proposed Period of Support [Form Page 5 (MS Word | PDF)] with the application.

Note: these two form pages have been modified. Specifically, the "Consortium/Contractual Direct Costs" budget row has been moved to above the "Subtotal Direct Costs" line.

For budget requests of $100,000 total or less, refer to the specific Modular Budget Instructions.

- Submit Form Page 4 and Form Page 5, and follow the specific non-modular instructions for SBIR or STTR, as applicable.

- Form Page 4 reflects the total direct costs, which include the total costs of any contractual costs, requested for the initial (first 12 months) Phase I or Phase II budget period. (F&A/indirect costs are requested on the Checklist Page.) Form Page 4 also reflects the fee/profit requested.

- Form Page 5 reflects the total direct costs plus fee for the entire project period. This form is also used to prepare the *narrative budget justification*.

- Do not include any items that are treated by the applicant organization as indirect costs according to a Federal rate negotiation agreement, except for those indirect costs included in consortium/contractual costs.

- Submit a separate detailed budget (Form Page 4) for each participating consortium/contractual organization. For each, label that page accordingly. If consortium activity exceeds one year, also include Form Page 5. See **Consortium/Contractual Costs** for specific instructions.

- Refer to the [SBIR or STTR Reminder Sheet]() before submitting the grant application.

F&A/Indirect Costs are to be shown on the Checklist Page. The TOTAL costs (sum of direct, F&A and fee) are to be shown on the Face Page in Items 7b and 8b.

Non-Modular SBIR Budget

SBIR Initial Budget Period (Form Page 4)

The following items pertain individually to the completion of Form Page 4 (Detailed Budget for Initial Budget Period – Direct Costs Only), to be completed by the small business concern.

Each item listed on Form Page 4 must be clearly justified on Form Page 5. List only the direct costs requested in this application. Do not include any items that are treated by the applicant organization as Facilities and Administrative (F&A) costs according to a Federal rate negotiation agreement, except for those F&A costs included in consortium/contractual costs.

Personnel

Name. Starting with the principal investigator, list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

Role on Project. Identify the role of each individual listed on the project. Describe their specific functions under Justification on Form Page 5. Provide budget narrative for ALL personnel by position, role, and level of effort. This includes any “to-be-appointed” positions.

Type of Appointment/Months. List the number of months per year reflected in an individual’s contractual appointment to the applicant organization. Unless otherwise noted, PHS staff assume that appointments at the applicant organization represent 12 months/100 percent time for each individual. If an appointment is less than full time, e.g., 50 percent time (i.e., 6 months), identify with an asterisk (*) and provide a full explanation under “Justification” on Form Page 5. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, for each appointment, identify and enter the number of months on separate lines. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period.

Percent of Effort on Project. For each individual at the applicant organization, list the percent of full-time effort to be spent on this project or use an asterisk (*) as described above if not full time. While a minimum percent effort is not stipulated for the principal investigator on an SBIR project, note that the principal investigator is the individual who is responsible for the scientific or technical aspects of the grant and for day-to-day management of the project.

Institutional Base Salary. The institutional base salary is defined as the annual compensation that the organization pays for the individual's employment, whether that individual's time is spent on research, administration, or other activities. Base salary excludes any income the individual may be permitted to earn outside of duties to the organization. Base salary may not be increased as a result of replacing corporate salary funds with grant funds.

An applicant organization may choose to leave this column blank. However, PHS staff will require this information prior to award.

Salary Requested. Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual’s institutional base salary by the percent of effort on this project. Explain under Justification on Form Page 5 if a lesser amount is requested (e.g., endowed position or institutional sources).

Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limitations, see the *Salary Cap Summary* on the NIH grants Web site or contact your office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

Fringe Benefits. Leave this column blank as *commercial (for-profit) organizations usually treat "fringe benefits" as indirect costs*. In certain cases, fringe benefits may be requested as a direct cost to the extent that they are treated consistently by the organization as a direct cost to all sponsors.

Totals. Calculate the totals for each position and enter the subtotals in each column where indicated.

The applicant organization and its subcontractor(s) may omit salaries and fringe benefits for individuals from copies of the application that are available to non-Federal reviewers. In such cases, replace the numbers with asterisks. You must show the subtotals. Provide one copy, for use only by PHS staff, with the asterisks replaced by the salaries and fringe benefits.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed on Form Page 5 under "Justification." Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Letters of commitment from collaborators and consultants must be submitted with the application, but are excluded from the Phase I 25-page limitation.

Equipment

Provide the total dollar amount requested. *List each item* of equipment separately. *Justify the request on Form Page 5*. Explain the need for any item that appears to be duplicated or equivalent to those listed in the "Resources" portion on these forms.

Supplies

Provide the total dollar amount requested. *Justify the request on Form Page 5*. Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. (Categories in amounts less than $1,000 do not have to be itemized.) If animals are to be purchased, state the species, the number to be used, their unit purchase cost, and their unit care cost.

Travel

Provide the total dollar amount requested. *Justify the request on Form Page 5*. Describe the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that agency policy requires that less than first-class air travel be used. Travel of a reasonable amount ($1,500-$2,000) may be proposed to attend conferences and similar meetings in the scientific field(s) of endeavor, to learn of new or emerging scientific interests of the PHS awarding components (for example, bioengineering), and to improve post award management. Travel to a scientific meeting in a foreign country is allowable, but this request should be thoroughly justified regardless of the dollar amount requested.

Patient Care Costs

The applicant organization may be reimbursed for inpatient and outpatient charges incurred incidentally to the proposed research. *Justify the request on Form Page 5*. Patient care costs do not include travel, lodging, and subsistence; request these costs in the "Other Expenses" category. Request consultant physician fees in the "Consultant Costs" category.

If inpatient and/or outpatient costs are requested, provide the names of any hospitals and/or clinics and the amounts requested for each on Form Page 5. *Justify the request on Form Page 5*.

State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, the PHS awarding component can approve a provisional rate. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of Other Support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers.

Other Expenses

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, patient participation incentives, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission when budgeted separately from salary/fringe benefits. **Justify costs on Form Page 5.**

Consortium/Contractual Costs

On the applicant organization's budget, list the *sum of all* consortium/contractual costs (separate lines provided for direct costs and F&A). *Justify the request on Form Page 5*.

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (F&A) costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

When F&A costs are requested by a consortium organization, enter the costs in the F&A cost category for each supplementary budget. Provide the F&A cost base and rate. Leave the direct cost category blank.

For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional page(s) after Form Page 5, numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)

Enter the "Subtotal Direct Costs for Initial Budget Period". Also enter this number in Item 7a of the Face Page.

Total Direct Costs for Initial Budget Period

Enter total direct costs for the Initial Budget Period (up to 12 months).

Fee

Enter the request for profit/fee as a *separate line item* below the "Total Direct Costs for Initial Budget Period." *Justify the request on Form Page 5*. A reasonable fee, not to exceed *7% of total costs* (direct and indirect) for each Phase (I and II) of the project, is available to small business concerns receiving awards under the SBIR/STTR program. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work.

The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

SBIR Entire Proposed Period of Support (Form Page 5)

On Form Page 5, enter in the first column the budget category totals of the "Initial Budget Period" costs from Form Page 4.

Phase I applicants requesting a budget period of one year or less need not complete additional years of support; however, you will need to use the lower section of Form Page 5 for your narrative "Budget Justification." Use continuation pages as necessary.

Applicants requesting more than one year of support must enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget, if applicable. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support. *Provide necessary justifications for the amount requested for profit/fee and other items described on the form*.

Enter in *Item 8a* on the Face Page, the amount for "Subtotal Direct Costs" as indicated on Form Page 5.

Enter in *Item 8b* on the Face Page, "Total Costs Requested for Proposed Period of Support" the *sum* of the following amounts: (1) "Total Direct Costs for Entire Project Period"; plus (2) Total profit/fee for Entire Proposed Project Period; plus (3) Total F&A costs as indicated on the Checklist Form Page.

SBIR applicants may proceed directly to the next section, Biographical Sketch.

Non-Modular STTR Budget

STTR Research Institution Budget Form Page (MS Word | PDF)

Submit Form Page 4 and Form Page 5, which are to be completed by the applicant small business concern, and submit the STTR Research Institution Budget Form Page, which is to be *completed by the single partnering research institution (RI)*, in accordance with the instructions below.

The STTR Research Institution Budget Form Page identifies costs pertaining to the portion of the work to be performed by the research institution for the *initial (up to 12 months)* STTR Phase I or Phase II project. If the project exceeds one year, the research institution must also use a *separate* Form Page 5 to identify its costs for future years.

Reminder. The single partnering research institution must certify *at the time of application* that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." Space has been provided on the form for the requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution upon signing the budget page.

STTR Initial Budget Period

On the Research Institution's Budget Page, provide information for Personnel, Consultant Costs, Equipment, Supplies, Travel, Patient Care Costs, Other Expenses, Total Direct Costs, Facilities and Administrative (F&A) Costs, and Total Costs associated with the research institution's portion of the budget in the same manner as described above under "Non-Modular SBIR Budget." Provide the F&A cost base and rate.

Also indicate the total direct costs and F&A costs in the field labeled "Consortium/Contractual Costs" on the Small Business Concern's Budget Page (Form Page 4). When the research institution requests F&A costs, these *costs are included as a direct cost for the Small Business Concern*.

Other Consortia/Subcontracts. Costs pertaining to arrangements for a portion of the project to be conducted by *other than* the "research institution" should be identified by way of photocopying budget Form Page 4 (and Form Page 5 if the budget exceeds one year) and completing it in the same manner as described above.

Justify costs pertaining to the research institution under "Justification" on the *Small Business Concern's Form Page 5*. Total costs of the portion of the project to be performed by the research institution are also to be shown in the Justification section of Form Page 5. If space is not available on the form, attach continuation page(s) for this purpose.

STTR Entire Proposed Project Period Form Page 5 *(MS Word | PDF)*

If the STTR project exceeds one year, use a *separate* Form Page 5 to identify costs pertaining to the portion of the project to be conducted by the research institution for the "Entire Proposed Project Period". *Identify the research institution's budget page by typing "Budget of Research Institution" at the top of Form Page 5*. Insert these additional pages *after* the budget pages of the small business concern (Form Page 4 and Form Page 5), numbering them sequentially. (Do not use 5a, 5b, 5c, etc.) Provide information for Personnel, Consultant Costs, Equipment, Supplies, Travel, Patient Care Costs, Other Expenses, Subtotal Direct Costs, Total Direct Costs, and Consortium/ Contractual Costs associated with the research institution's portion of the budget in the same manner as described above.